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| 10/625,359 | 07/23/2003 | Daniel M. Deaton | 900001-2115 | 8226 |
| 59945 7590 02/04/2009 KOS PHARMACEUTICALS, INC. 1 CEDAR BROOK DRIVE CRANBURY, NJ 08512-3618 | | | | |
| EXAMINER | | | | |
| PATEL, NIHIR B | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,359

Applicant(s)

DEATON ET AL.

Examiner

NIHIR PATEL

Art Unit

3772

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-15, 45-48, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-15, 45-48, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on March 10th, 2008, with respect to claims 1-6, 10-14, 45-48, 55 and 56 have been fully considered and are persuasive. The previous rejection of the office action dated September 10th, 2007 has been withdrawn.

Response to Amendment

2. The amendment filed on March 10th, 2008 is acknowledged by the examiner. The amendment comprises cancellation of claims 7-9, 16-44 and 49-54.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1-6, 10-15, 45, 46, 55 and 56** are rejected under 35 U.S.C. 102(b) as being anticipated by Burns et al. (US 5,284,133).

5. **As to claim 1**, Burns teaches an apparatus that comprises at least one canister **10** (see **figures 1, 4A and 4B; col. 7 lines 50-60 and col. 8 lines 60-65**) containing the medication to be dispensed, the canister being movable in a first position and a second position (see **col. 9 lines 10-30**); a mouthpiece **14** providing a point of dispensation for the medication from the canister to a user when the canister is moved in the first direction (see **figures 1 and 4B; col. 7 lines 50-60**);

a switch means **28** for completing an electrical circuit when the canister moves in the first direction and opening the electrical circuit when the canister moves in the second direction (**see figure 2; col. 8 lines 1-30**), wherein the switch means is oriented to enable operational connectivity with the canister or canister discharge (**see col. 8 lines –30**); a counter module for performing a count upon the closure of the electrical circuit and displaying a dispensation history of the medication in the at least one canister (**see col. 10 lines 5-20**); a ramp **44** that is contacted by a ferrule portion of the canister in a direction substantially non-axial to the first direction and which acts upon the switch means when the canister is moved in the first direction (**see figures 4A and 4B; col. 10 lines 5-20**); and a seal isolating the counter from the mouthpiece and the canister to prevent contamination (**The guide tube 12 and the cover of the controller is defined as the seal; see figures 4A and 4B; col. 10 lines 5-20**).

6. **As to claim 2**, Burns teaches an apparatus wherein the dispensation history includes the number of doses of medication remaining in the canister (**see col. 8 lines 14-31; it is inherent that since Burns teaches an apparatus where the controller 24 is programmed for certain actuations at certain times that it would inherently also include the number of doses of medication remaining in the canister since the device of Burns also has a locking device**).

7. **As to claim 3**, Burns teaches an apparatus wherein the dispensation history includes the number of doses taken of a dosage sequence (**see col. 8 lines 14-31**).

8. **As to claim 4**, Burns teaches an apparatus wherein the dispensation history includes the number of doses taken over a period of time (**see col. 8 lines 14-31**).

9. **As to claim 5**, Burns teaches an apparatus wherein the period of time can be varied by a user (**see col. 12 lines 30-40**).

10. **As to claim 6**, Burns teaches an apparatus wherein the dispensation history includes time since the last dispensing of the medication (**see col. 8 lines 14-31**).
11. **As to claim 10**, Burns teaches an apparatus wherein the switch means includes an electrically conductive contact imbedded in the seal (**see col. 9 lines 10-30**).
12. **As to claim 11**, Burns teaches an apparatus wherein at least portion of the counter module is disposed in the mouthpiece (**see col. 12 lines 5-25**).
13. **As to claim 12**, Burns teaches an apparatus wherein at least a portion of the counter module is disposed external to the mouthpiece (**see figure 4A and col. 12 lines 15-25**).
14. **As to claim 13**, Burns teaches an apparatus wherein the seal also isolates the ramp and switching means (**see figures 4A and 4B**).
15. **As to claim 14**, Burns teaches an apparatus wherein the switch means is mounted on a circuit board (**see col. 8 lines 5-15**).
16. **As to claim 15**, Burns teaches an apparatus wherein the seal is made of conductive material (**inherently all materials are conductive some more than others**).
17. **As to claim 45**, Burns teaches an apparatus wherein the counter, ramp and seal are formed in a common component (**see figures 4A and 4B; col. 10 lines 5-20**).
18. **As to claim 46**, Burns teaches an apparatus that further comprises a sump for a nozzle of the canister wherein the counter, ramp, seal and sump are formed as a common component (**see figures 4A and 4B**).
19. **As to claim 55**, Burns teaches an apparatus wherein the ramp further permits travel of the ferrule over the ramp to allow opening of the canister valve after acting on the switch means (**see figures 4A and 4B; col. 8 lines 14-31**).

20. **As to claim 56**, Burns teaches an apparatus that comprises at least one canister **10** (see **figures 1, 4A and 4B; col. 7 lines 50-60 and col. 8 lines 60-65**) containing the medication to be dispensed, the canister being movable in a first and second direction; a switch means **28** for completing an electrical circuit when the canister moves in the first direction and opening the electrical circuit when the canister moves in the second direction (see **figure 2; col. 8 lines 1-30**), wherein the switch means is oriented to enable operational connectivity with the canister or canister discharge (see **col. 8 lines -30**); and a ramp **44** that is contacted by a ferrule portion of the canister in a direction substantially non-axial to the first direction and which acts upon the switch means when the canister is moved in the first direction (see **figures 4A and 4B; col. 10 lines 5-20**).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims **47 and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133).
24. **As to claims 47 and 48**, Burns substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a common component that is injection molded. The method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Nihir Patel/
Examiner, Art Unit 3772
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